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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,309	10/15/2001	Tony Cruz	033352-010	4565

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FISH & RICHARDSON P.C.  
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REDWOOD CITY, CA 94063

EXAMINER
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LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/978,309

**Applicant(s)**

CRUZ ET AL.

**Examiner**

Samuel W Liu

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2003 and 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 1-17-03
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-28-03
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

**DETAILED ACTION**

The response filed 30 October 2003, which cancels claims 7-9 and 15-33, amends claims 1-2, 5, 10 and 12-14, has been entered.

The following pending claims 1-6 and 10-14 are examined in this Office action. Note that the grounds of objection and/or rejection not explicitly stated and/or set forth below are withdrawn.

***IDS***

The references lists in IDS of PTO 1449 Form filed 7 November 2003 has been received and considered.

Also, the examiner acknowledges receipt of the IDS filed 25 February 2003. An initialed copy of all of the properly cited references is attached to the instant office action. The references cited in the IDS thereof have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO-1449 form, must be filed within the set period for reply to this Office Action.

***Claim Rejections - 35 USC §103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 and 10-14 are rejected under 35 U.S.C. 103(a) as being obvious over Turley, E. A. et al. (WO 9738098) (A) taken with Charo, I. F. et al. (US Pat. No. 5707815).

Turlupin et al. (A) teach a polypeptide sequence comprising the sequence of SEQ ID NO:74 of the instant application (see the amino acid sequence of human RHAMM (receptor hyaluronic acid mediated motility) at Turley et al. (A), page 46, Table 3). Residue 443 to 684 of Turley sequence are identical to residues 1-242 of the full-length SEQ ID NO:74 of the instant application except that position 154 isoleucine of the instant application is leucine for the sequence of Turley et al. Note that the currently amended claims recite the open language “consisting essentially of” (equivalent to “comprising”) opposed to the closed language “consisting of”.

Charo et al. teach that *conservative* substitution of leucine for isoleucine does not have major effect on the folding structure and activity of the subject polypeptide (see column 4, lines 10-15). Thus, the Turley et al. in view of Charo et al. teaching is obvious variations over the composition of application claims 1 and 10-14.

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Claims 10-14 as written set forth the same composition as that of claims 2-10 wherein the RHAMM polypeptide is an antigen for the antibody irrespective of the preamble "vaccine" that has not patentable input on the claimed composition thereof. Please note that the current invention is directed to the composition not a method of use the composition thereof, and the intended use (e.g., treating inflammatory neurological disorder) has no patentable weight *per se* associated with the claimed composition which structure and biological activity will not be altered due to the use of the RHAMM polypeptide for inflammatory neurological disorder state, e.g., multiple sclerosis.

One of ordinary skill in the art would have been motivated to combine the above references as one is inextricably led to the Turley et al. (A) in view of Charo et al. teaching regarding conservative substitution of isoleucine with leucine to arrive at the claim invention.

Claims 2-6 are rejected under 35 U.S.C. 103(a) as being obvious over Turley, E. A. et al. (WO 9738098) (A) taken with Charo, I. F. et al. (US Pat. No. 5707815) as applied to claim 1 above in view of Turley, E. A. et al. (EP 0721012) (B).

Turley et al. in view of Charo et al. teach the obvious variation of RHAMM polypeptide of SEQ ID NO:74 of the current application (see the above statement). Also, Turley et al. (A) teach the RHAMM polypeptide being used in protein therapy for treating a disease state (see pages 22-23), as applied to claims 2-6 of the instant application. Yet, Turley does not explicitly teach a pharmaceutical composition comprising the claimed RHAMM polypeptide.

Turley, E. V et al. (B) teach a pharmaceutical composition (see page 31, lines 1-17) comprising the isolated human RH polypeptide for treating any disorder arising from unwanted

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or excessive stimulation of cell-associated RHAMM (see page 31, lines 16-17). Thus, Turley et al. (A) teaching in view of Turley et al. (B) is obvious over claims 2-6 of the instant application.

One of ordinary skill in the art would have combined the teachings of the above references because Turley et al. (B) teaches the pharmaceutical composition comprising the RHAMM polypeptide for treating a disorder state associated with abnormally regulated RHAMM. When combined, the skilled artisan would have successfully arrived at the current invention the claimed polypeptide, i.e., pharmaceutical composition comprising the RHAMM polypeptide thereof. Thus, the claimed invention was *prima facie* obvious to make and use at the time it was made.

The response to the rejection under 35 USC 103

The response file 30 October 2003 asserts that the Turley's reference (A) does not teach or suggest the full-length RHAMM protein (i.e., SEQ ID NO:74) disclosed in the instant claims (see pages 30-31). Applicants' argument is unpersuasive because the instant independent claim 1 recites the open language "consisting essentially of" (equivalent to "comprising") opposed to the closed language "consisting of". Thus, the Turley's teaching stated above is applicable to the claims.

Also, the response argues that Charo et al. reference is not qualified as an obviousness prior art as the reference merely teaches conservative replacement of leucine with isoleucine (see page 30, the second to the last paragraph, and page 31, the first and the second paragraph). Charo et al. do suggest that *conservative* substitution of leucine residue for isoleucine residue in the protein does not influence the protein folding and function thereof. Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that whether the

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conservative substitution (Leu → Ile) would have a significant impact on the claimed composition. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980). Therefore, the Applicant's argument is deemed unpersuasive.

***Provisional Rejection - Obviousness Type Double Patenting***

Claim 1 of this application conflict with claims 34 of Application No. 09685010. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this

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application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected under the judicially created doctrine of double patenting over claims 34 of copending Application No. 09685010. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Claim 34 of Application 09685010 sets forth a polypeptide comprising all or portion of domains of RHAMM; the claim language as written encompasses the SEQ ID NO:74 of the instant application since SEQ ID NO:74 is a portion of full-length RHAMM protein. Thus, the instant application and copending application claim is obvious variation.

It is noted that page 31 of the response filed 30 October 2003 requests abeyance of the obvious-type double patenting rejection at a later date or until allowable subject matter is indicated. Note that no allowable subject matter can be indicated with a standing ground of rejection. Thus, it is suggested that applicant file the appropriate terminal disclaimer.



***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

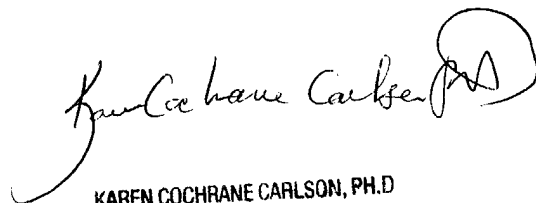
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703-308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

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Samuel Wei Liu, PhD.

December 10, 2002



KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER